DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
DIRECT RX

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DIPHENHYDRAMINE HYDROCHLORIDE

OTC - ACTIVE INGREDIENT SECTION

(in each capsule)

Diphenhydramine HCl 25 mg

OTC - PURPOSE SECTION

Antihistamine

INSTRUCTIONS FOR USE SECTION

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
runny nose
itchy nose or throat
sneezing
itchy, watery eyes

WARNINGS SECTION

Do not use with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
When using this product

- you may get very drowsy
- avoid alcoholic drinks
- alcohol, sedatives & tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

In case of overdose, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION SECTION

- adults and children 12 years and over: take 1 to 2 capsules every 4-6 hours; not more than 6 doses in 24 hours
- children under 12 years: ask a doctor

OTHER SAFETY INFORMATION

- store at 15-30 °C (59-86 °F)
- protect from moisture
- For 1000 Count: This is a bulk package. Dispense contents in a tight, light-resistant container with a child-resistant closure as defined in the USP

INACTIVE INGREDIENT SECTION

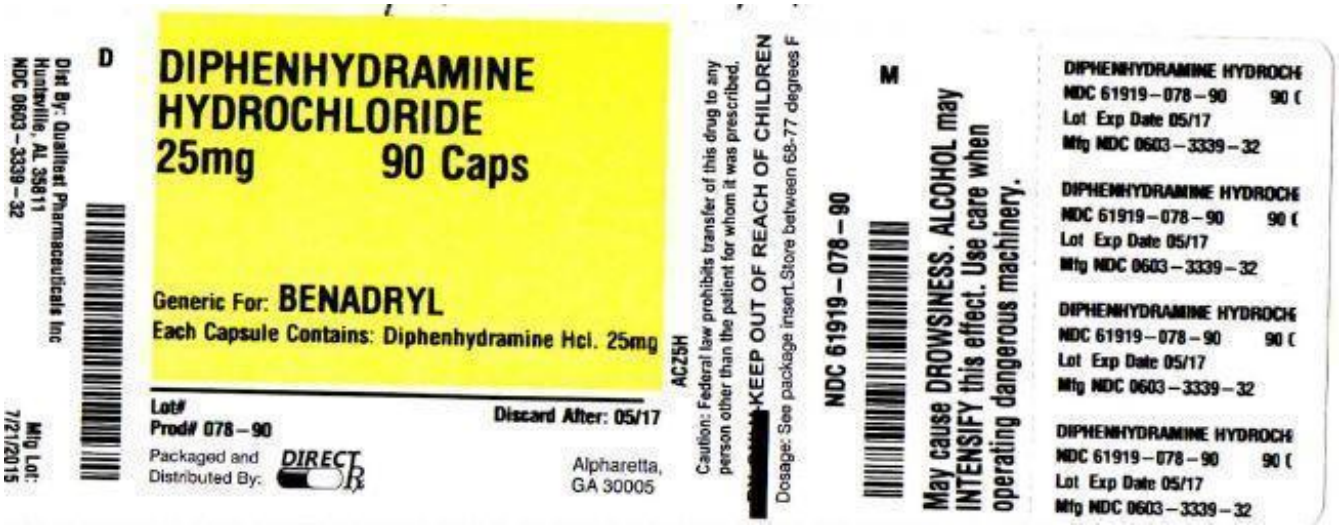
benzyl alcohol, butylparaben, D&C red# 28, edible black ink, FD&C bule #1, FD&C red# 40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium laurel sulfate

OTC - QUESTIONS SECTION

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS MISSING OR DAMAGED

Distributed by: Qualitest Pharmaceuticals, Inc.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-078(NDC:0603-3339)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	pink	**Score**	no score
Shape	capsule	**Size**	14mm
Flavor		**Imprint Code**	AP;020
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-078-20	20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:61919-078-90	90 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:61919-078-30	30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2015	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(61919-078) , repack(61919-078)

Revised: 8/2015 DIRECT RX